In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-1132V

DONALD HOLMBERG, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: June 23, 2023

Alison H. Haskins, Maglio Christopher & Toale, PA, Sarasota, FL, for Petitioner.

Jennifer A. Shah, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW REGARDING ONSET[1]

On March 29, 2021, Donald Holmberg filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleged that following his receipt of an influenza ("flu") vaccine on January 28, 2020, he developed Guillain-Barré syndrome ("GBS"). Petition at ¶¶ 1, 24-25. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

[1] Because this ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Petitioner filed the medical records and the signed declaration[3] required under the Vaccine Act at the outset of the case, and periodic updates thereafter. Exs. 1-14 filed March 30, 2021 (ECF Nos. 6-7); *see also* Exs. 16-20 (ECF Nos. 11, 13); Exs. 21-22 (ECF No. 17); Exs. 23-26 (ECF No. 21).

On January 13, 2022, Respondent initiated settlement discussions by "invit[ing] Petitioner to submit a reasonable demand." Status Report (ECF No. 22). After the parties reached an impasse, however, Petitioner asked for my preliminary opinion as to whether his onset of symptoms was consistent with a Table flu/GBS injury. *See* Scheduling Order (ECF No. 26). After the status conference, the parties were informed that: "Based on my review of the record to date and the [then] current lack of any specific objections from Respondent, I ha[d] not identified onset to be a significant issue." *Id.* at 1. The parties made a further attempt at informal resolution, which was unsuccessful. Afterwards, Petitioner and three other individuals provided their recollections about the underlying facts. Exs. 27-30 filed August 24, 2022 (ECF No. 28).[4] The parties then briefed entitlement. Petitioner's Motion for Findings of Fact and Conclusions of Law filed August 24, 2022 (ECF No. 29) ("Brief"); Respondent's Combined Report Pursuant to Vaccine Rule 4(c) and Response filed October 7, 2022 (ECF No. 32) ("Response"); Petitioner's Reply dated October 28, 2022 (ECF No. 34) ("Reply").

The parties' briefing raises a single dispute: whether Petitioner's onset occurred within, or just outside of, the outer limit for a Table GBS injury. For the following reasons, I find that (under the "more likely than not" preponderant standard) onset occurred *no more than* 42 days after receipt of the flu vaccine.

I. Applicable Legal Standards

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in

[3] Rather than an affidavit, the statement provided by Petitioner is a declaration signed under penalty of perjury as required pursuant to 28 U.S.C.A. § 1746.

[4] These declarations were also signed under penalty of perjury. *See* note 3. Petitioner and his wife's declarations at Ex. 27-28 were most likely prepared like those of his other witnesses in summer 2022, but they are not dated. In late October 2022, Petitioner and his wife dated and refiled the identical declarations. Ex. 39-40. This opinion will cite to the original filings.

the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

The Vaccine Injury Table creates a presumption of causation for GBS meeting certain criteria, including onset "3 – 42 days (not less than 3 days *and not more than 42 days)"* after receipt of a seasonal influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(D) (emphasis added). Also relevant to onset, the Table explains that GBS is generally marked by "bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs." 42 C.F.R. § 100.3(c)(15)(ii)(A).[5]

Table flu/GBS claims have often been dismissed for failure to establish proper onset. *See, e.g.*, *Randolph v. Sec'y of Health & Hum. Servs.*, No. 18-1231V, 2020 WL 542735, at *8 (Fed. Cl. Spec. Mstr. Jan. 2, 2020) (finding GBS onset at the earliest occurred 76 days post-vaccine, thus necessitating dismissal of the Table claim); *Benenhaley v. Sec'y of Health & Hum. Servs.*, No. 20-0545V, 2022 WL 17974426 (Fed. Cl. Spec. Mstr. Nov. 28, 2022) (onset 108 – 109 days post-vaccine).

In adjudicating off-Table (actual causation) flu-GBS claims, special masters have recognized that a later onset may be medically acceptable. *Barone v. Sec'y of Health & Hum. Servs.*, No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (accepting onset up to 56 days post-vaccine, for actual causation); *see also Spayde v. Sec'y of Health & Hum. Servs.*, No. 2021 WL 686682, at *18-19 (Fed. Cl. Spec. Mstr. Jan. 27, 2021) (finding actual causation based on onset 49 days post-vaccine). However, such claims obviously do not receive the Table presumption of causation – or the initial benefit of the "lookback provision". *Randolph*, 2020 WL 542735, at *8-9 (holding that a flu-GBS claim with onset outside of the Table timeframe, filed outside of the typical three-year limitations period, was untimely and must be dismissed).

[5] Pertaining to the three most common variants of the injury, which together comprise the vast majority of GBS cases recognized in North America and Europe. In the present case, Petitioner has not alleged – nor do I perceive from my own review of the evidence – development of a fourth, less common variant which does not require limb weakness. 42 C.F.R. § 100.3(c)(15)(iii).

II. Relevant Evidence

I have reviewed all of the evidence filed to date. This ruling, however, is limited to resolving only a single fact issue: the most likely onset for Petitioner's GBS. Accordingly, I will only summarize or discuss evidence that directly pertains to this issue, as informed by both parties' respective citations to the record and their arguments. Specifically:

- ***Medical Records.*** On January 28, 2020, Petitioner received the subject flu vaccine at a Veterans' Affairs Medical Center ("VAMC") in Erie, Pennsylvania. Ex. 1 at 1-2.

- Forty-five (45) days later, on Friday, March 13, 2020,[6] Petitioner presented to the Warren General Hospital ("WGH") emergency room. WGH hospitalist Ralph Meloro, M.D., recorded: "[Petitioner] states his right hip has been hurting on and off for years, however, it has worsened in the past few days to the point where he can't walk. He denies trauma to the area. He describes the pain as 'sharp and achy' and non-radiating, but states he has numbness in [sic, and?] tingling in the legs and feet b/l. He feels 'weak and wobbly' and is unable to raise his right leg off of the bed. Rest improves the pain. He fell two days ago and again this morning because his legs felt heavy and he lost his balance." Ex. 2 at 92; *see also id.* at 64, 78 (triage assessments).

- Petitioner's symptoms of numbness and tingling in his lower and upper extremities worsened further – prompting the WGH medical providers to consult an outside neurologist, Harshit Shah, M.D., at Saint Vincent Hospital. It was agreed that Petitioner should be transferred to the latter hospital, where he would receive a "higher level of care." *See* Ex. 2 at 54 (WGH discharge summary).

- On Tuesday, March 17, 2020, a St. Vincent hospitalist, Rachel Wilkerson D.O., conducted the admitting history and physical. Ex. 16 at 479. She recorded: "[Petitioner] reports that 67 [sic?] days ago he was in his normal state of health. He states he was walking 3-4 miles every single morning. He states that about six days ago, he noticed that his feet did not feel normal. He states he was still able to walk without any difficulty, however over the course of the day it became more and more difficult. He states that he fell carrying his wife's bags. He states that he felt like his legs were throwing his balance off. He did not injure himself in that fall. He reports that four days ago in the morning, he did not go on his walk, he states that he was walking in his house and fell on the carpet. He states that he was able to use a walker that they had around the house without any issue. He presented

[6] Because 2020 was a leap year, February had 29 days.

to the emergency department, where he was put in a wheelchair and admitted. The following morning Saturday, he could still use the walker in the morning, but by the end of the day his arms had become too weak to support himself his hands on the walker." *Id.* at 480.

- Dr. Wilkerson also recorded Petitioner's report of "a flu shot and pneumonia shot at the end of January/ early February, and he received shingles vaccine two weeks after that. He did not have any immediate side effects from either of these vaccines." Ex. 16 at 480.[7]

- Dr. Wilkerson assessed: "Unclear etiology but with relatively acute onset and progression over 3-4 days… Will consult neurology for assistance and recommendations." Ex. 16 at 494.

- Also on Tuesday, March 17, 2020, the St. Vincent neurologist Dr. Shah – who had initiated Petitioner's transfer from WGH to facilitate a higher standard of care – met with him directly for the first time. Ex. 16 at 499. Dr. Shah recorded: "According to the patient, he was in normal state of health until last Tuesday. Last Tuesday, patient noticed onset of numbness in his toes in bilateral feet. Patient did not make much out of the symptoms at that time… the numbness slowly progressed to involve both feet… he started having difficulty in coordinating his movements because of the numbness in both lower extremities… he was having difficulty ambulation and balance because of the numbness. Patient did have a fall on Thursday when he lost his stepping because of the numbness. At that time, patient did not hit his head or lose consciousness… the numbness continued to progress and reached bilateral knees by Friday, he was also having weakness in both his legs. Around the same time, patient also noticed that numbness had begun in bilateral upper extremities starting in his fingers… he [fell] again on the 13th in his house for which he went to Warren General Hospital to get himself tested for gait difficulty and right hip pain." *Id.*[8]

- On March 24, 2020, Petitioner was transferred from St. Vincent's Hospital to an inpatient rehabilitation hospital, where he remained for approximately one month. Afterwards, he received outpatient treatment for his GBS, including neurology

[7] Petitioner received a shingles vaccine at the VAMC on February 7, 2020. Ex. 1 at 1. However, that vaccine is not covered under the Program. Neither the parties nor my own review identified receipt of a pneumonia vaccine in early 2020.

[8] Within this quote, an ellipsis ("…") is used only when Dr. Shah repeated the phrase "According to the patient."

follow-ups and physical therapy. However, neither the parties' briefing nor my own review has identified any additional medical records, beyond what is cited above, that shed light on the onset determination.

- ***Declarations.*** Over two years after the events in question, Petitioner recalled: "In the few days before [his] birthday on March 5, 2020, [he] noticed a tingling and numbness in [his] toes and feet. [His] legs felt heavy…" Ex. 27 at ¶ 4. The symptoms "continued into [his] lowers legs and up to both knees over the next week." *Id.* He began "losing motor function in both of [his] hands" and "shortly after that, [he] started to have trouble with [his] balance and walking." *Id.* Petitioner "did not want to see a doctor for these issues." *Id.* "However, [his] balance and other problems and [he] started to fall." *Id.* "[He] had several near-falls and at least two actual falls during the second week of March, right after [his] birthday." *Id.*

- Petitioner recalled: "On the morning of March 13, 2020, [he] fell again in front of [his] wife and landed on [his] left thigh on the carpet… [He] finally broke down and decided to go to the emergency room…" Ex. 27 at ¶ 5.

- Petitioner also described his preexisting post-traumatic stress syndrome ("PTSD") "particularly as relates to doctors and medical treatment," stemming from his military service; his anxiety and terror surrounding his GBS symptoms and hospitalization; and isolation because his wife was not permitted to stay with him in the hospital due to the emerging COVID-19 pandemic. Ex. 27 at ¶¶ 3-10.

- Two family members offered similar recollections. First, his wife recalled noticing sometime "before" his birthday, Petitioner began "moving more slowly and acting unsteady on his feet." Ex. 28 at ¶ 3. She recalled that on his birthday, Petitioner "basically sat on the couch all night." *Id.* at ¶ 4.

- Petitioner's adult son (and the son's three teenage children) lived approximately fifteen (15) minutes away. Ex. 29 at ¶ 2. The family gathered "typically every Sunday," and "also frequently to socialize, watch baseball, and other activities" in addition to birthdays and other family celebrations. *Id.* The son similarly recalled that Petitioner began to appear unsteady and off-balance "shortly before [his] birthday" in 2020. *Id.* at ¶ 4.

- The final declaration from a neighbor/ tenant is less specific about the key timing – describing a change in Petitioner's condition "in early March 2020, around his birthday." Ex. 30 at ¶ 3.

III. Analysis

As noted above, Petitioner avers that he began experiencing tingling, numbness, and heaviness in his lower extremities "a few days" before his March 5th birthday (37 days post-vaccine); progressing to two falls and his hospital presentation the following week. Brief at 7, 10. However, the medical records are quite detailed in describing that he was in his "normal state of health" and that he disclaimed any difficulties with his lower extremities (to wit, that he was "walking 3-4 miles every single morning") until either **March 10th or 11th, 2020 (42 or 43 days post-vaccine)**, with the first fall occurring two days later. *See* Ex. 16 at 479-80, 499. While recognizing that GBS is an alarming condition and that Petitioner was apprehensive of medical providers, *see* Reply at 4, it is not evident why such a specific account would be inaccurate and omit approximately a week of earlier and escalating symptoms.

Petitioner also avers that the later declarations (Exs. 27-30) only serve to *supplement* the medical records. Reply at 7. But to the contrary, the declarations propose an onset of numbness, tingling, and heaviness in his lower extremities just before his March 5th birthday – in direct conflict with the far more contemporaneous medical records, which state that the same symptoms began on March 10th or 11th. The later declarations, while consistent with one another, are not sufficiently clear and compelling to win the day.

The medical records themselves are somewhat inconsistent with one another with regards to onset. While the earliest records are from WGH (*see, e.g.*, Ex. 2 at 92), Petitioner was transferred to St. Vincent to receive a higher level of care just four days later. The St. Vincent records are also more detailed in describing the onset of the earliest and more subtle neurological symptoms. Within the St. Vincent records, the hospitalist Dr. Wilkerson recorded onset as "about six days ago," which was March 11, 2020. Ex. 16 at 479. In contrast, the neurologist Dr. Shah recorded onset as "last Tuesday," which was March 10, 2020. *Id.* at 499. Dr. Shah recorded the symptoms as beginning with numbness in his toes bilaterally, progressing to both feet, then numbness and balance issues, then falls on March 12th[9] and 13th, 2020. *Id.* This record is fairly contemporaneous to the events in question; detailed; and created by the medical provider most qualified in the assessment and treatment of the relevant medical condition. It is also pertinent that Dr. Shah had previously corresponded with the WGH providers and arranged Petitioner's transfer to St. Vincent. Thus, Dr. Shah's record warrants somewhat more weight.

[9] I recognize that the WGH hospitalist Dr. Meloro recorded that Petitioner's first fall was "two days ago" which would have been on March 11, 2020. Response at 10 (citing Ex.2 at 92). While that record was created earlier in time, the St. Vincent neurologist's record is more specialized and detailed in assessing his GBS – and the key date is not for the first fall, but for the onset of the more subtle neurological symptoms that *predate* the fall.

Given the foregoing, it is reasonable to conclude on this record that "more likely than not" Petitioner's GBS onset occurred on March 10, 2020, or 42 days post-vaccination. Trustworthy medical records support that onset, even though other records suggest one occurring a day later.

Conclusion

Petitioner has established the onset of GBS not more than 42 days after receipt of a seasonal flu vaccine.

Petitioner avers that he has presented preponderant evidence for all other criteria for a Table flu/GBS injury. Brief at 10-13. Petitioner has also articulated his position regarding appropriate compensation (specifically pain and suffering, and past unreimbursable expenses) for said injury. *Id.* at 13-28.

Accordingly, within 30 days, by Monday, July 24, 2023, Respondent shall propose further proceedings in either a status report or a revised Rule 4(c) report which incorporates my findings of fact pertaining to onset. Respondent shall also report whether he would like to file a response to Petitioner's briefing on damages, and if so, propose a deadline for the same.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master